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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/612,192 | 07/02/2003 | Ranajit Pal | 00711CIP | 4134 |
| 26418 | 7590 | 05/15/2007 | | |
| REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650 | | | EXAMINER PENG, BO | |
| | | | ART UNIT 1648 | PAPER NUMBER |
| | | | MAIL DATE 05/15/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/612,192

Applicant(s)

PAL ET AL.

Examiner

Bo Peng

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the reply filed 20 February 2007. Claims 1-20 are pending. Claims 8-14 and 16-20 are withdrawn from consideration as nonelected inventions. Claims 1-7 and 15 are considered in this Office action.

35 USC § 101 Utility

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. The rejection of Claim 15 under 35 U.S.C. 101, for lacking either a credible asserted utility or a well-established utility, **is withdrawn**.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of Claim 15 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement **is maintained** for the reason of record.

6. Applicant argues that Claim 15 is meant to be used to help develop a vaccine for HIV. The specification need not specify how to create a marketable vaccine. The specification need

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only provide information sufficient to inform one of ordinary skill in the art how to practice the invention for its cited utility. Using flu vaccine consisting of multiple substances which together inoculate people against multiple strains of influenza, Applicant asserts that the instant specification has set forth how to use the invention to assist in the creation of a vaccine.

7. Applicant's argument is considered but is found not persuasive. The specification must be enabling as of the filing date (see MPEP 2164.05(a) [R-2]). An invention is not a scientific hypothesis and should be definite and in currently available form at the time the application was filed. In order to provide proof of utility with regard to drugs and their uses, either clinical or *in vivo* or *in vitro* data, or a combination of these can be used. However, the data must be such as to convince one of ordinary skill in the art that the proposed utility is sufficiently established. See *in re Irons*, 340 F. 2d 924, 144 USPQ 351 (CCPA 1965), *Ex parte Krepelka*, 231 USPQ 746 (PTO Bd. Pat. App & Inter. 1986) and *Ex pane Chwang*, 231 USPQ 751 (PTO Bd. Pat. App & Inter. 1986). In the instant case, the *in vitro* data presented in the specification is insufficient to convince one of ordinary skill in the art that the claimed vaccine can be effective for its intended use.

8. It is known in the art that the quasispecies nature of HIV and the plasticity of the HIV-1 genome contribute to its ability to alter itself in every replication cycle, and thereby acquire mutations to escape immune pressures, contributes to the difficulties in producing a vaccine. Neither the specification nor prior art has provided sufficient teaching to show the asserted HIV vaccine strategy can overcome the extraordinary variability of HIV, resulting an HIV vaccine. Therefore, the instant specification does not "provide information sufficient to inform one of ordinary skill in the art how to practice the invention for its recited utility".

9. The rejection of Claims 1-7 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is **maintained** for the reason of record.
10. The rejection of Claims 1-7 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope, is **maintained** for the reason of record.
11. Applicant argues that it is not required that the scope of “an equivalent thereof” be specifically limited because “or an equivalent thereof” in Claim 1 is merely to make it abundantly clear that Claim 1 also includes equivalents, as is inherently included under the theory of doctrine of equivalent.
12. Applicant’s argument is not convincing. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is “not sufficient characterization for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP § 2163. Here, the claimed immunogen complex comprising gp120 covalently bonded to a fragment of CD4 is a synthetic compound. One of ordinary skill in the art can not recognized what is “inherently included” in a man made compound without a structure characterization or correlation between function and structure. Therefore, the claim lacks written description.
13. Because of the lack of written description of the claimed fusion proteins and “cryptic epitopes”, one of ordinary skill in the art can not make the instant fusion molecules.

Double Patenting

14. The rejection of Claims 1-7 on the ground of nonstatutory obviousness-type double

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patenting over Claim 1 of US 5,843,454, and Claim 1 of US 5,518,723 **is maintained**. Applicant acknowledges the rejection and does not wish to prematurely respond.

Remarks

15. No claim is allowed. **THIS ACTION IS MADE FINAL.**

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

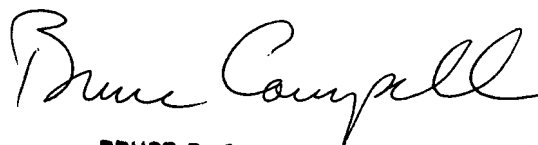
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP

Bo Peng, Ph.D.
May 4, 2007



**BRUCE R. CAMPPELL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**